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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,261	07/30/2003	Syed F. A. Hossainy	50623.276	8699

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EXAMINER

HAGOPIAN, CASEY SHEA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/630,261

Applicant(s)

HOSSAINY ET AL.

Examiner

Casey Hagopian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-23 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/11/05.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Receipt is acknowledged of applicant's Amendment/Remarks filed 7/29/2005 and Information Disclosure Statement filed 7/11/2005.

MAINTAINED REJECTIONS

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-10 and 12-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldstein et al. (USPN 6,143,037). Goldstein discloses compositions for coating medical devices comprising pharmaceutical agents and block copolymers and methods of making thereof (abstract; column 1). Goldstein also discloses various polymers including ethylene oxide, propylene oxide, polyalkylene glycols such as polyethylene glycol, and poly(ϵ -caprolactone) (column 14, lines 30-34; column 28, lines 50-52). More specifically, Goldstein discloses copolymer blocks of ABA and BAB with specific examples being poly(ϵ -caprolactone)-block-poly(ethylene oxide)-block-poly(ϵ -caprolactone) and poly(ethylene oxide)-block-poly(ϵ -caprolactone)-block-poly(ethylene oxide) (column 28, lines 56-60; table 1). Goldstein also discloses stents as a suitable coated medical device (column 31, lines 37) as well as various methods of applying the coating to the medical device (column 25, line 54 – column 31, line 24). Even though

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the reference is silent to one of the moieties producing a biological response and the other moiety provides a structural functionality, it is the position of the examiner that these properties are dependant upon the moieties themselves. The reference clearly discloses the block copolymers of claims 5-8 and 16-19 of the instant application as mentioned above in the rejection, therefore the composition is expected to have the same physiochemical properties as well as the same effect as the compositions set forth in the instant application. As such, it is the examiner's position that the composition advanced by Goldstein anticipates the compositions enumerated in the instant claim set. These disclosures render the claims anticipated.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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6. Claims 11 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein et al. in view of Pinchuk et al. (US 2002/0107330 A1). Goldstein includes the elements discussed above in paragraph 3 of the rejection. However, Goldstein does not disclose diazenium diolate. Pinchuk teaches a coated medical device, the coating comprising an AB block copolymer and a therapeutic agent (abstract). Pinchuk also teaches the specific agent diazenium diolate, a nitric oxide donor that promotes wound healing and treats restenosis (paragraphs 0103, 0120 and 0124). One of ordinary skill in the art would have reasonable expectation and motivation that the product would be a coated medical device capable of treating a patient for restenosis with a sustained release dosage of diazenium diolate. In Goldstein it would have been obvious to someone skilled in the art to include diazenium diolate as suggested by Pinchuk in order to treat restenosis in a patient.

7. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein et al. in view of Taylor et al. (WO 97/16133). Goldstein includes the elements discussed above in paragraph 3 of the rejection. However, Goldstein does not disclose phosphoryl choline or polyaspirin. Taylor teaches a polymeric coated stent, the coating comprising, preferably, phosphoryl choline (abstract) in order to minimize unfavorable interactions such as thrombosis in a patient (page 6, line 11 – page 7, line 1). One of ordinary skill in the art would have reasonable expectation and motivation that the product would decrease the chances that a patient implanted with a coated stent would

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develop thrombosis. In Goldstein it would have been obvious to someone skilled in the art to include phosphoryl choline as suggested by Taylor.

Response to Arguments

8. Applicant's arguments, see pages 25-26, filed 7/29/2005, with respect to the rejection of claims 3-7 and 14-18 under 35 U.S.C 112 have been fully considered and are persuasive. The rejection of claims 3-7 and 14-18 under 35 U.S.C 112 has been withdrawn.

9. Applicant's arguments filed 7/29/2005 have been fully considered but they are not persuasive. Applicant states that Goldstein does not teach the limitation "wherein at least one of the A or B blocks comprise poly(ethylene glycol)" and thus have amended the claims to include this limitation into the independent claims. However, the previous office action discusses the elements of Goldstein and includes poly(ethylene glycol) as one of the A or B blocks (see paragraph 3 above and column 28 of Goldstein). For these reasons, it is the position of the examiner that Goldstein does teach the limitation in question and therefore, all claims remain rejected.

10. Examiner notes that applicant does not address any other issues in conjunction with the art rejections beyond what is discussed above in paragraph 9 of the rejection.

Conclusion

11. All claims have been rejected; no claims are allowed.

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12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on M-F from 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

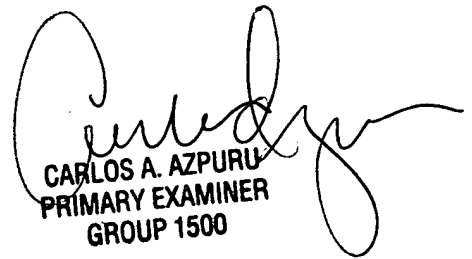
For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).



Casey Hagopian
Examiner
Art Unit 1615



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